

HISTORY OF INTRAUTERINE DEVICES*

LAZAR MARGULIES, M.D.

Lecturer, Department of Obstetrics and Gynecology
The Mount Sinai School of Medicine of the City University of New York
New York, N.Y.

IT does not appear probable that intrauterine devices (IUD) were used before the 20th century. High perinatal and infant mortality, religious restrictions, and the possibly dire consequences of manipulations in the uterus in preantiseptic times must have restrained responsible physicians from using this method on human beings. Probably everyone has heard the legend about inserting pebbles into the uteri of camels before taking them on a trek across a desert.

The first paper on the IUD was published in Germany in 1909. Dr. Richard Richter¹ reported insertions of a ring made of silkworm gut into the uterus. He cut off the two ends at the level of the external cervical os in order preserve the possibility of checking and removal. Richter's publication passed unheeded, probably for reasons mentioned above.

At that time cervico-uterine stem pessaries or wishbone pessaries made of hard rubber or various metals competed with vaginally placed cervical caps and later with the Dutch Messinga pessary. The former were condemned by teaching institutions because of frequent ascending inflammation, especially gonorrhea, and because of the assumption that they caused early abortion of fertilized eggs. In spite of this, a few were patented, supposedly for treatment of infertility and dysmenorrhea.

In the mid-1920s Karl Pust² recommended a silkworm ring placed in the uterus with a stiff cervical extension of a tightly wound silk thread and a glass button to cover the cervix. Neither he nor Graefenberg mentioned Richter's paper.

At about the same time, Ernest Graefenberg³ of Berlin dared to cut vilified cervical extensions from the silkworm-gut ring. However, for reasons of roentgen visualization he at first attached a silver wire to the ring and later wound the silver wire all around. Ultimately he re-

*Presented at a *Symposium on the IUD* held by the Section on Obstetrics and Gynecology of the New York Academy of Medicine April 17, 1974.

placed the silkworm gut by a spirally coiled metal ring composed of an alloy of copper, nickel, and zinc (the so-called German silver). Pure silver rings had to be abandoned because silver was absorbed and led to gingival argyrosis of the gums, analogous to the lead line.

The Graefenberg ring was widely used in England and all British dependencies from Canada to Australia but not in continental Europe and in the United States. When Graefenberg, Lehfeld, and Herbert Hall immigrated to the United States in the mid-1930s they were cautioned by Robert Dickinson, a pioneer of contraception, not to risk using this technique. In this era contraception was considered a method of convenience rather than one of necessity.

Even Dr. Alan Guttmacher's attitude toward the IUD was tarnished by reports of untoward experiences. A paper, "On the Present status of Contraception," written in collaboration with Dr. Hilliard Dubrow,⁴ published in the March-April 1959 issue of the *Journal of the Mount Sinai Hospital*, contains the following sentence: "Intra-uterine devices are mentioned only to be thoroughly condemned because of their ineffectiveness, their potential source for infection and irritation, as well as their carcinogenic potentialities."

In November 1958, Dr. John Rock gave the memorial lecture in honor of Dr. Isidor Rubin at The Mount Sinai Hospital. Having worked in the infertility clinic of The Mount Sinai Hospital, I attended the lecture in order to learn of new ideas in infertility. Instead, Dr. Rock talked only about the dangers of overpopulation—the expression "population explosion" had not yet been coined—and of the work done with Dr. Gregory Pincus on *antifertility* drugs.

I remembered the Graefenberg ring, which a few doctors here were using surreptitiously. Not being able to obtain them from the manufacturer, I checked the available literature of the past three decades and found only the paper by Dr. Mary Halton, Dr. Robert Dickinson, and Dr. Christopher Tietze⁵ describing a method of intra-uterine contraception. Dr. Halton used silkworm gut. She wound it around her finger, pressed the ring into a gelatine capsule and pushed the capsule into the uterine cavity, where the gelatine liquefied and the thread spread out. Her statistics, compiled by Dr. Tietze, reported a failure rate of only 1.1% in 266 patients and 468 woman-years.

I tried to adopt the method but replaced the silkworm gut with thin polyethylene tubing into which I injected a radio-opaque solution

and which I sealed at both ends. Dr. Guttmacher permitted me to try the method out on patients who had had tubal ligation. Inserting them in 26 women between January and April 1959, I found the method disappointing not only because of bleeding and expulsion but mainly because of the pain caused by insertion of a 6 mm. capsule through the cervix. I removed all the tubing in May, as scheduled, and considered a different method of insertion. I visualized a possibility of slipping a device through a tube which had a diameter of only 3-4 mm.; this would not necessitate dilatation of the cervix. After one year of trials with many designs and materials I came upon polyethylene, which had just been issued as a powder. It could be mixed with barium, could be molded and stretched, and would return to its originally molded form.

In August 1969 Dr. Wilhelm Oppenheimer published his article in the *American Journal of Obstetrics and Gynecology*.⁶ This essay suggested possible revival of the IUD. In April 1960, in *Excerpta Medica*, there was an excerpt of Ishihama's⁷ paper, published originally in April 1959, in the *Yokohama Medical Journal*. Ishihama's article revealed—unknown to us until then—the large utilization of IUDs in Japan in 32 different patterns, variations of Graefenberg-Ota rings. The statistics were impressive: 20,000 women, more than twenty years of usage, without a single case of endometrial carcinoma! Both papers allayed our apprehension about this predicted danger of the IUD. As far as I know, the only instance of endometrial carcinoma among the scores of millions of users, was published by Dr. William B. Ober.⁸

In September 1960, before a panel consisting of Dr. Guttmacher, Dr. Aqviles Sobrero, and Dr. Tietze, I presented the inserter tube, the coil, and a hystero-gram of my wife, who had submitted to the first insertion. Since I wanted to gain a few months of experience on my private patients, who would return more readily with complaints or ejections than clinic patients, I did not initiate the IUD clinic at Mount Sinai until January 1961. Dr. Guttmacher decided that any pregnancy occurring with the device in situ could be interpreted in the hospital as "failure of a research method." We had quite a few until it was decided that no insertion would be done after the 12th day of the cycle.

The Population Council of New York became interested in the method and called the First Conference on the IUD for April 30th-May 1st, 1962.⁹ Fifty interested researchers were invited, among them

Oppenheimer and Ishihama. Under the chairmanship of Dr. Warren Nelson and Dr. Alan Guttmacher, the participants discussed the pros and cons of a cervical extension, the timing of the insertion, the causes of failure and expulsion, and possible modes of action. I presented results on my first 500 patients treated with and without a beaded tail, which I had added to the coil in January 1962. Dr. J. Lippes reported his experience in 170 patients with the shell of plastic OTA rings and 100 loops. Dr. Herbert Hall reported the modification of the Graefenberg ring by replacing the alloy with stainless steel.

The next year brought the Birnberg "BOW" and the double coil, the so-called safety-coil. The devices were widely distributed; the Population Council, the Ford Foundation, and the Pathfinder Fund supported the distribution and evaluation of accumulated experience through the Cooperative Statistical Program of the National Committee of Maternal Health under the directorship of Dr. Tietze. A large amount of investigation on the mode of action was also undertaken. In October 1964, when the *Second International Conference on the IUD* was convoked by the Population Council,¹⁰ there were more than 150 participants. The efficacy of the method was no longer questioned, and presterilized individual packaging (to avoid infections on insertion) started to gain acceptance.

Subsequent years brought the development of the so-called second generation of IUDs, such as the Maizlin spring, the Incon ring, the Antigon, the "M" device, the LEM, the Dalkon Shield, and more than a dozen others. Because some deaths following the insertion or wearing of an IUD were reported, the council for the Food and Drug Administration (FDA) ordered a survey, which was conducted by Dr. Roger B. Scott of Case Western University. Dr. Scott sent out 8,500 questionnaires and received some 6,450 answers, or 75.8%.^{11, 12} Ten deaths and 15 instances of intestinal obstruction due to the slipping of intestine through the device after perforation were reported, most of them with the so-called open devices. Ectopic pregnancy occurred once in 20 pregnancies (about 10 times the normal rate), a biased statistic which does not take into consideration that more than 90% of women wearing a device did not become pregnant. However, in the vast majority of the 56,000 reported insertions the IUD was well tolerated and the FDA approved the use of the method in 1968 but "advised" against the use of "closed" devices. Recently the FDA re-

called the Maizlin rings because of dangerous complications. The so-called "second-generation devices" did not necessarily prove better; some are still being evaluated, such as those which include a silastic capsule containing progesterone (originated by Dr. Antonio Scommegna¹³) and on which evaluation is not yet available. Others are worse. Retention is only one requirement of a good IUD. Others are absence of pain on insertion and removal, absence of cramps, bleeding, and—last but not least—absence of pregnancy. I think that this meeting would not be held if either Lippes or I had to advise women to use contraceptive jelly with our devices.

The breakthrough did come, however, five years ago when Jaime Zipper¹⁴ et al. of the Worcester Foundation discovered the inhibitive action of metallic copper and Howard Tatum utilized it as an adjunct to his T-device—reducing the pregnancy rate from 18% to about 1%. New shapes like the copper-7 and possibly old devices in a new copper dress, or somehow reshaped, promise a brighter future for the reliability and thus the acceptance of the IUD.

Despite mountains of papers and scores of ideas and hypotheses, we have not yet reached a generally accepted fail-proof theory on the mode of action of the IUD. Starting with the mechanistic suggestion of accelerated transport of ova through the tube, which I proposed at the *First Conference on the IUD* in 1962¹⁵ and which was so perfectly proved by experiments of Luigi Mastroianni and C. Hong-sanand¹⁶ on pergonalized monkeys and continuing to the piranha-like macrocytes gobbling up the spermatozoa, we seem to return to Warren Nelson's suggestion that some enzymes may prevent implantation of the ovum. Prostaglandins have been the focus of research during the past few years. Recently Saksena and Harper¹⁷ of the Worcester Foundation have reported that in rabbits the IUD not only stimulates local formation of prostaglandin-F as preventing implantation, but that the process can be reversed and that implantations take place when a measured amount of Indomethanin, which is a proved inhibitor of prostaglandin, is injected for a few days before implantation.

REFERENCES

1. Richter, R.: Ein Mittel zur Verhuetung der Konzeption. *Deutsch. Med. Wschr.* 35:1525-27, 1909.
2. Pust, K.: Ein brauchbarer Frauen-schutz. *Deutsch. Med. Wschr.* 49:952-53, 1923.
3. Graefenberg, E.: Silk as Anticoncipient. *Geburtenregelung—Vortraege und Ver-*

- handlungen des Aerztekursus vom 28-30 Dezember 1928*, Bendix, K., editor. Berlin, Selbstverlag, 1929.
4. Dubrow, H. and Guttmacher, A.F.: On the present status of contraception. *J. Mount Sinai Hosp.* April-May, 1959.
 5. Halton, M., Dickinson, R.L., and Tietze, C.: Contraception with intrauterine silk coil. *Human Fert.* 413:10-13, 1949.
 6. Oppenheimer, W.: Prevention of pregnancy by the Graefenberg ring method: A revaluation after 28 years' experience. *Amer. J. Obstet. Gynec.* 78:446-54, 1959.
 7. Ishihama, A.: Clinical studies on intrauterine contraception, especially the present state of contraception in Japan and the experience in the use of intrauterine rings. *Yokohama Med. J.* 10:89, 1959.
 8. Ober, W. B., Sobrero, A. J., Karmar, R., and Gold, S.: Endometrial morphology and polyethylene contraceptive devices. *Obstet. Gynec.* 32:782-93, 1968.
 9. Tietze C., and Levit, S., editors: *Intrauterine Contraceptive Devices*, Proceedings of the first conference, New York City, April 30-May 1, 1962. Amsterdam, Excerpta Medica Int. Cong. Series No. 54, 1962.
 10. Segal, S. J., Southam, A. L., and Shaffer, K. D., editors: *Intrauterine Contraception*. Proceedings of the second conference, New York City, October 2-3, 1964. Amsterdam, Excerpta Medica Int. Cong. Series No. 86, 1965.
 11. Scott, R. B.: Critical illness and deaths associated with intrauterine devices. *Obstet. Gynec.* 31:322-27, 1968.
 12. Scott, R. B.: A survey of deaths and critical illness in association with the use of intrauterine devices. *Int. J. Fert.* 13:297-300, 1968.
 13. Scommegna, A., Pandya, G. N., Christ, M., Lee, A. W., and Cohen, M. R.: Intrauterine administration of progesterone by a slow-releasing device. *Fert. Ster.* 21:201-10, 1970.
 14. Zipper, J. A., Tatum, H. J., Pastene, L., Medel, M., and Rivera, M.: Metallic copper as an intrauterine contraceptive adjunct to the "T" device. *Amer. J. Obstet. Gynec.* 105:1274-78, 1969.
 15. Margulies, L. C. In: *Intrauterine Contraceptive Devices*, Tietze C. and Levit, S., editors. Amsterdam, Excerpta Medica Int. Cong. Series, No. 54, 1962.
 16. Mastroianni, L. and Hongsanand, C.: Mechanism of action of the Intrauterine Contraceptive Device in the Primate: Tubal Transport of Ova and Distribution of Spermatozoa. In: *Intrauterine Contraceptive Devices*, Tietze C. and Levit, S., editors. Amsterdam, Excerpta Medica Int. Cong. Series No. 54, 1962, pp. 194-97.
 17. Saksena, S. K., and Harper, M. J. K.: Prostaglandin-mediated action of intrauterine devices: F-Prostaglandins in the uterine horns of pregnant rabbits with unilateral intrauterine devices. *Fert. Ster.* 25:121-26, 1974.